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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No.: 7365

Art Unit: 1623

Examiner: *To be assigned*

Atty. Docket: 0942.4980006/RWE/MTT

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**Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document AS4 cited on Form PTO 1449:

Document AS4 is in a foreign language. An English language translation is not readily available.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

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be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.


This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Brian J. Del Buono  
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for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: October 11, 2002

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 50,424	09/24/1981	Europe			Yes No
	AM1	EP 0 84,796	01/11/1983	Europe			Yes No
	AN1	EP 0 144 914	11/29/1984	Europe			Yes No
	AO1	EP 0 119 448	02/10/1984	Europe			Yes No
	AP1	EP 0 201 184	03/27/1986	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>1</u>	Abe, T., et al., "Specific inhibition of influenza virus RNA polymerase and nucleoprotein gene expression by circular dumbbell RNA/DNA chimeric oligonucleotides containing antisense phosphodiester oligonucleotides," <i>FEBS Lett.</i> 425:91-96, Elsevier Science Publishers B.V. (1998)
	AS	<u>1</u>	Austermann, S., et al., "Inhibition of Human Immunodeficiency Virus Type 1 Reverse Transcriptase by 3'-Blocked Oligonucleotide Primers," <i>Biochem. Pharmacol.</i> 43:2581-2589, Elsevier Science (1992)
	AT	<u>1</u>	Barnes, W.M., "The fidelity of Taq polymerase catalyzing PCR is improved by an N-terminal deletion," <i>Gene</i> 112:29-35, Elsevier Science Publishers B.V. (1992)

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	AL2	EP 0 237 362	03/13/1987	Europe			Yes No
	AM2	EP 0 258 017	08/21/1987	Europe			Yes No
	AN2	EP 0 329 822	08/26/1988	Europe			Yes No
	AO2	WO 88/10315	12/29/1988	WIPO			Yes No
	AP2	WO 89/06700	07/27/1989	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	2	Bonnet, G., et al., "Thermodynamic basis of the enhanced specificity of structured DNA probes," <i>Proc. Natl. Acad. Sci. USA</i> 96:6171-6176, National Academy of Sciences of the USA (May 1999)	
AS	2	Cardullo, R.A., et al., "Detection of nucleic acid hybridization by nonradiative fluorescence resonance energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 85:8790-8794, National Academy of Sciences of the USA (1988)	
AT	2	Chédin, F., et al., "Novel homology of replication protein A in Archaea: implications for the evolution of ssDNA-binding proteins," <i>TIBS</i> 23:273-277, International Union of Biochemistry and Elsevier Trends Journal (1998)	

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	AL3	WO 90/03446	04/5/1990	WIPO			Yes No
	AM3	WO 92/06188	04/16/1992	WIPO			Yes No
	AN3	WO 92/06200	04/16/1992	WIPO			Yes No
	AO3	WO 92/14845	09/03/1992	WIPO			Yes No
	AP3	EP 0 684 315	03/13/1995	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>3</u>	Clegg, R.M., et al., "Fluorescence Resonance Energy Transfer Analysis of the Structure of the Four-Way DNA Junction," <i>Biochem.</i> 31:4846-4856, American Chemical Society (1992)	
AS	<u>3</u>	Clegg, R.M., "Fluorescence Resonance Energy Transfer and Nucleic Acids," <i>Methods Enzymol.</i> 211:353-388, Academic Press Inc. (1992)	
AT	<u>3</u>	Clegg, R.M., et al., "Observing the helical geometry of double-stranded DNA in solution by fluorescence resonance energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 90:2994-2998, National Academy of Sciences of the USA (1993)	

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	AL4	WO 96/10640	04/11/1996	WIPO			Yes No
	AM4	EP 0 436 644 B1	04/17/1996	Europe			Yes No
	AN4	EP 0 795 612 A2	09/17/1997	Europe			Yes No
	AO4	WO 98/35060	08/13/1998	WIPO			Yes No
	AP4	WO 98/47921	10/29/1998	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>4</u>	Flaman, J.-M., et al., "A rapid PCR fidelity assay," Nucl. Acids Res. 22:3259-3260, Oxford University Press (1994)	
AS	<u>4</u>	Forster, Z., "Experimentelle und theoretische Untersuchung des zwischenmolekularen Übergangs von Elektronenanregungsenergie," Z. Naturforsch 4A:321-327, Verlag der Zeitschrift für Naturforschung (1949)	
AT	<u>4</u>	Gerard, G.F., et al., "cDNA Synthesis by Moloney Murine Leukemia Virus RNase H-Minus Reverse Transcriptase Possessing Full DNA Polymerase Activity," FOCUS 14:91-93, Life Technologies, Inc. (1992)	

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	AL5	WO 99/10366	03/04/1999	WIPO			Yes No
	AM5	EP 0 795 612 A3	03/24/1999	Europe			Yes No
	AN5						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Holland, P.M., et al., "Detection of specific polymerase chain reaction product by utilizing the 5'→3' exonuclease activity of <i>Thermus aquaticus</i> DNA polymerase," <i>Proc. Natl. Acad. Sci. USA</i> 88:7276-7280, National Academy of Sciences of the USA (1991)
	AS	5	Houts, G.E., et al., "Reverse Transcriptase from Avian Myeloblastosis Virus," <i>J. Virol.</i> 29:517-522, American Society for Microbiology (1979)
	AT	5	Idriss, H., and Stammers, D.K., "Inhibition of HIV-1 Reverse Transcriptase by Defined Template/Primer DNA Oligonucleotides: Effect of Template Length and Binding Characteristics," <i>J. Enzyme Inhib.</i> 8:91-112, Harwood Academic Publishers GmbH (1994)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Jendis, J., et al., "Inhibition of Replication of Fresh HIV Type 1 Patient Isolates by a Polypurine Tract-Specific Self-Complementary Oligodeoxynucleotide," <i>AIDS Res. Human Retrov.</i> 12:1161-1168, Mary Ann Leibert, Inc., Publishers (1996)
	AS	<u>6</u>	Ju, J., et al., "Fluorescence energy transfer dye-labeled primers for DNA sequencing and analysis," <i>Proc. Natl. Acad. Sci. USA</i> 92:4347-4351, National Academy of Sciences of the USA (1995)
	AT	<u>6</u>	Kainz, P., et al., "Specificity-Enhanced Hot-Start PCR: Addition of Double-Stranded DNA Fragments Adapted to the Annealing Temperature," <i>BioTechniques</i> 28:278-282, Eaton Publishing Company (February 2000)

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	AR	7	Kelly, T.J., et al., "Identification and characterization of a single-stranded DNA-binding protein from the archaeon <i>Methanococcus jannaschii</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 95:14634-14639, National Academy of Sciences of the USA (1998)
	AS	7	Kleppe, K., et al., "Studies on Polynucleotides. XCVI. Repair Replications of Short Synthetic DNA's as Catalyzed by DNA Polymerases," <i>J. Mol. Biol.</i> 56:341-361, Academic Press, Inc. (1971)
	AT	7	Kotewicz, M.L., et al., "Isolation of cloned Moloney murine leukemia virus reverse transcriptase lacking ribonuclease H activity," <i>Nucl. Acids Res.</i> 16:265-277, Oxford University Press (1988)

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	AR	8	Kuwasaki, T., et al., "Hairpin Antisense Oligonucleotides Containing 2'-Methoxynucleosides with Base-Pairing in the Stem Region at the 3'-end: Penetration, Localization, and Anti-HIV Activity," <i>Biochem. Biophys. Res. Commun.</i> 228:623-631, Academic Press, Inc. (1996)
	AS	8	Kwong, D.Y., et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <i>Proc. Natl. Acad. Sci. USA</i> 86:1173-1177, National Academy of Sciences of the USA (1989)
	AT	8	Lawyer, F.C., et al., "High-level Expression, Purification, and Enzymatic Characterization of Full-length <i>Thermus aquaticus</i> DNA Polymerase and a Truncated Form Deficient in 5' to 3' Exonuclease Activity," <i>PCR Meth. Appl.</i> 2:275-287, Cold Spring Harbor Laboratory Press (1993)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	2	Lee, L.G., et al., "Allelic discrimination by nick-translation PCR with fluorogenic probes," <i>Nucl. Acids Res.</i> 21:3761-3766, Oxford University Press (1993)
	AS	2	Luo, G., et al., "Inhibition of influenza viral polymerases by minimal viral RNA decoys," <i>J. Gen. Virol.</i> 78:2329-2333, Society for General Microbiology (1997)
	AT	2	Lyamichev, V., et al., "Structure-Specific Endonucleolytic Cleavage of Nucleic Acids by Eubacterial DNA Polymerases," <i>Science</i> 260:778-783, Association for the Advancement of Science (1993)

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AR	<u>10</u>	Maury, G., et al., "Template. Phosphorothioate Oligonucleotides Duplexes As Inhibitors of HIV-1 Reverse Transcriptase," <i>Biochem. Biophys. Res. Commun.</i> 186:1249-1256, Academic Press, Inc. (1992)
AS	<u>10</u>	Mullis, K., et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," <i>Cold Spring Harbor Symp. Quant. Biol.</i> 51:263-273, Cold Spring Harbor Laboratory Press (1986)
AT	<u>10</u>	Nakaya, T., et al., "Decoy Approach Using RNA-DNA Chimera Oligonucleotides To Inhibit the Regulatory Function of Human Immunodeficiency Virus Type 1 Rev Protein," <i>Antimicrobiol. Agents Chemother.</i> 41:319-325, American Society For Microbiology (1997)

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	AR	<u>11</u>	Nazarenko, I.A., et al., "A closed tube format for amplification and detection of DNA based on energy transfer," Nucl. Acids Res. 25:2516-2521, Oxford University Press, Oxford, England (1997)
	AS	<u>11</u>	Ozaki, H., and McLaughlin, L.W., "The estimation of distances between specific backbone-labeled sites in DNA using fluorescence resonance energy transfer," Nucl. Acids Res. 20:5205-5214, Oxford University Press, Oxford, England (1992)
	AT	<u>11</u>	Panet, A., and Khorana, H.G., "Studies on Polynucleotides. The Linkage of Deoxyribopolynucleotide Templates to Cellulose and its Use in Their Replication," J. Biol. Chem. 249:5213-5221, American Society of Biological Chemists (1974)

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AR	<u>12</u>	Paris, P.L., et al., "Probing DNA sequences in solution with a monomer-excimer fluorescence color change," Nucl. Acids Res. 26:3789-3793, Oxford University Press (1998)	
AS	<u>12</u>	Saiki, R.K., et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," Science 239:487-491, Association for the Advancement of Science (1988)	
AT	<u>12</u>	Sarin, P.S., et al., "Inhibition of acquired immunodeficiency syndrome virus by oligodeoxynucleoside methylphosphonates," Proc. Natl. Acad. Sci. USA 85:7448-7451, National Academy of Sciences of the USA (1988)	

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>13</u>	Schneider, D.J., et al., "High Affinity ssDNA Inhibitors of the Reverse Transcriptase of Type 1 Human Immunodeficiency Virus," <i>Biochem.</i> 34:9599-9610, American Chemical Society (1995)
AS	<u>13</u>	Selvin, P.R., "Fluorescence Resonance Energy Transfer," <i>Methods Enzymol.</i> 246:300-334, Academic Press Inc. (1995)
AT	<u>13</u>	Selvin, P.R., and Hearst, J.E., "Luminescence energy transfer using a terbium chelate: Improvements on fluorescence energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 91:10024-10028, National Academy of Sciences of the USA (1994)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>14</u>	Soltis, D.A., and Skalka, A.M., "The $\alpha$ and $\beta$ chains of avian retrovirus reverse transcriptase independently expressed in <i>Escherichia coli</i> : Characterization of enzymatic activities," <i>Proc. Natl. Acad. Sci. USA</i> 85:3372-3376, National Academy of Sciences of the USA (1988)
AS	<u>14</u>	Stein, C.A., et al., "Physicochemical properties of phosphorothioate oligodeoxynucleotides," <i>Nucl. Acids Res.</i> 16:3209-3221, Oxford University Press (1988)
AT	<u>14</u>	Tyagi, S., and Kramer, F.R., "Molecular Beacons: Probes that Fluoresce Upon Hybridization," <i>Nature Biotechnol.</i> 14:303-309, Nature Publishing Co. (1996)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	15	Wang, Y., et al., "Rapid Sizing of Short Tandem Repeat Alleles Using Capillary Array Electrophoresis and Energy-Transfer Fluorescent Primers," <i>Anal. Chem.</i> 67:1197-1203, American Chemical Society (1995)
	AS	15	Wu, D.Y., et al., "Allele-specific enzymatic amplification of $\beta$ -globin genomic DNA for diagnosis of sickle cell anemia," <i>Proc. Natl. Acad. Sci. USA</i> 86:2757-2760, National Academy of Sciences of the USA (1989)
	AT	15	Wu, D.Y., et al., "The Ligation Amplification Reaction (LAR)—Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <i>Genomics</i> 4:560-569, Academic Press (1989)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>16</u>	Xu, D., et al., "Melting and Premelting Transitions of an Oligomer Measured by DNA Base Fluorescence and Absorption," <i>Biochem.</i> 33:9592-9599, American Chemical Society (1994)
	AS	<u>16</u>	Yamana, K, et al., "Fluorescent-labeled oligonucleotides that exhibit a measurable signal in the presence of complementary DNA," <i>Nucl. Acids Symp. Ser.</i> 27:135-136, IRL Press Ltd. (1992)
	AT	<u>16</u>	"Amplifluor™ Universal Amplification & Detection System," Intergen Company Catalog, 4 pages, Purchase, NY (1999)

EXAMINER	DATE CONSIDERED
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

#9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No. 7365

OCT 15 2002

Art Unit: 1623

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Examiner: *To be assigned*

Atty. Docket: 0942.4980006/RWE/MTT

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

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This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
for: Robert W. Esmond  
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Date: October 11, 2002

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FORM PTO-1449  FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN5	WO 00/56916	09/28/2000	WIPO			Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	17	Ailenberg, M., and Silverman, M., " Controlled Hot Start and Improved Specificity in Carrying Out PCR Utilizing Touch-Up and Loop Incorporated Primers (TULIPS)," <i>Biotechniques</i> 29:1018-1024 (minus advertisement pages), Eaton Publishing Co. (November 2000)
AS	17	Ehlen, T., and Dubeau, L., "Detection of <u>Ras</u> Point Mutations By Polymerase Chain Reaction Using Mutation-Specific, Inosine-Containing Oligonucleotide Primers," <i>Biochem. Biophys. Res. Commun.</i> 160:441-447, Academic Press, Inc. (1989)
AT	17	Kaboev, O.K., et al., "PCR hot start using primers with the structure of molecular beacons (hairpin-like structure)," <i>Nucl. Acids Res.</i> 28:e94 (two pages), Oxford University Press (November 2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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George S. Bardmesser  
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Rodney G. Maze  
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\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Admitted only in Texas  
•Practice Limited to  
Federal Agencies

October 11, 2002

**WRITER'S DIRECT NUMBER:**

(202) 371-2560

**INTERNET ADDRESS:**

RESMOND@SKGF.COM

Commissioner for Patents  
Washington, D.C. 20231

Re: U.S. Utility Patent Application  
Appl. No. 10/026,952; Filed: December 27, 2001  
For: **Primers and Methods for the Detection and Discrimination of Nucleic Acids**  
Inventors Nazarenko *et al.*  
Our Ref: 0942.4980006/RWE/MTT

Hand Carry to  
Art Unit 1623

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Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. List of cited references on Form PTO-1449 (16 sheets);
3. A copy of each reference cited on Form PTO-1449 (70 references);
4. First Supplemental Information Disclosure Statement;
5. List of cited references on Form PTO-1449 (1 sheet);
6. A copy of each reference cited on Form PTO-1449 (4 references);
7. Second Supplemental Information Disclosure Statement;
8. List of cited references on Form PTO-1449 (2 sheets);
9. A copy of each reference cited on Form PTO-1449 (4 references);
10. Third Supplemental Information Disclosure Statement;
11. List of cited references on Form PTO-1449 (2 sheets);
12. A copy of each reference cited on Form PTO-1449 (6 references);
13. Fourth Supplemental Information Disclosure Statement;
14. List of cited references on Form PTO-1449 (6 sheets);
15. A copy of each reference cited on Form PTO-1449 (19 references);
16. Fifth Supplemental Information Disclosure Statement;
17. List of cited references on Form PTO-1449 (1 sheet);

Commissioner for Patents  
October 11, 2002  
Page 2

18. A copy of each reference cited on Form PTO-1449 (3 references); and
19. One (1) Return Postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Brian J. Esmond*  
for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893  
*Req. No. 42,473*

RWE/MTT/dnk  
Enclosures

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SKGF Rev. 2/15/02 dcw

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No. 7365

Art Unit: 1623

Examiner: *To be assigned*

Atty. Docket: 0942.4980006/RWE/MTT

**RECEIVED****OCT 15 2002****TECH CENTER 1600/2900****Second Supplemental Information Disclosure Statement**Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

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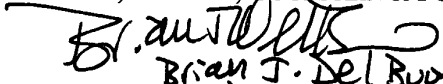
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Respectfully submitted,

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for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893  
*Brian J. Del Buono  
Reg. No. 43,473*

Date: October 11, 2002

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FORM PTO-1449 <u>SECOND SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL6	WO 98/02449	01/22/1998	WIPO			Yes No
	AM6	EP 0 881 302 A2	12/02/1998	Europe			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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EXAMINER

DATE CONSIDERED

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FORM PTO-1449  <u>SECOND SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>				ATTY. DOCKET NO. 0942.4980006/RWE/MTT		APPLICATION NO. 10/026,952	
				APPLICANT Nazarenko et al.			
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	A05	EP 0 709 466 A2	05/01/1996				Yes No
	AP5	EP 0774 516 A2	05/21/1997				Yes No
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
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#11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No. 7365

Art Unit: 1623

Examiner: *To be assigned*

Atty. Docket: 0942.4980006/RWE/MTT

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**Third Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Second Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Brian J. Del Buono*  
Reg. No. 42,473

for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: October 11, 2002

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FORM PTO-1449  <b>THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>18</u>	Rye, H.S., et al., "Stable fluorescent complexes of double-stranded DNA with bis-intercalating asymmetric cyanine dyes: properties and applications," <i>Nucl. Acids Res.</i> 20:2803-2812, Oxford University Press (1992)
	AS	<u>18</u>	Varani, G., "Exceptionally Stable Nucleic Acid Hairpins," <i>Annu. Rev. Biophys. Biomol. Struct.</i> 24:379-404, Annual Reviews Inc. (1995)
	AT	<u>18</u>	Walder, R.Y., et al., "Use of PCR primers containing a 3'-terminal ribose residue to prevent cross-contamination of amplified sequences," <i>Nucl. Acids Res.</i> 21:4339-4343, Oxford University Press (1993)

EXAMINER	DATE CONSIDERED
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449  <b>THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>				ATTY. DOCKET NO. 0942.4980006/RWE/MTT		APPLICATION NO. 10/026, 752	
				APPLICANT Nazarenko et al.		FILING DATE December 27, 2001	
				GROUP 1623		TECH CENTER 1600/2900	

U. S. PATENT DOCUMENTS							
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	AP					Yes No	

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	19	Wang, G.T., et al., "Design and Synthesis of Neew Fluorogenic HIV Protease Substrates Based on Resonance Energy Transfer," <i>Tetrahedron Lett.</i> 31:6493-6496, Pergamon Press PLC (1990)
	AS	19	Yamamoto, N. and Okamoto, T., "A rapid detection of PCR amplification product using a new fluorescent intercalator; the pyrylium dye, P2," <i>Nucl. Acids Res.</i> 23:1445-1446, Oxford University Press (1995)
	AT	19	International Search Report of International Application No. PCT/US00/17085, mailed May 23, 2001

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

#12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No. 7365

Art Unit: 1623

Examiner: *To be assigned*

Atty. Docket: 0942.4980006/RWE/MTT

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OCT 15 2002

**Fourth Supplemental Information Disclosure Statement**

TECH CENTER 1600/2900

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fourth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Third Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.


Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Fourth Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Brian J. Del Buono  
Reg. No. 42,472

for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: October 11, 2002

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Washington, D.C. 20005-3934  
(202) 371-2600

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 0942.4980006/RWE/MTT		APPLICATION NO. 10/026, 852	
				APPLICANT Nazarenko et al.		<b>RECEIVED</b> OCT 15 2002	
				FILING DATE December 27, 2001		GROUP 1623	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN6	WO 97/39008	10/23/1997	WIPO			Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	20	Blok, H.J. and Kramer, F.R., "Amplifiable hybridization probes containing a molecular switch," <i>Mol. Cell. Probes</i> 11:187-194, Academic Press, Ltd. (1997)				
	AS	20	Giesendorf, B.A.J., et al., "Molecular beacons: a new approach for semiautomated mutation analysis," <i>Clin. Chem.</i> 44: 482-486, American Association for Clinical Chemistry (1998)				
	AT	20	Haas, S., et al., "Primer design for large scale sequencing," <i>Nucl. Acids Res.</i> 26:3006-3012, Oxford University Press (1998)				
EXAMINER					DATE CONSIDERED		
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,892
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	21	Kostrikis, L.G., et al., "Spectral Genotyping of Human Alleles," <i>Science</i> 279:1228-1229, American Association for the Advancement of Science (1998)
AS	21	Kramer, F.R. and Lizardi, P.M., "Replicatable RNA reporters," <i>Nature</i> 339:401-402, Macmillan Journals Ltd. (1989).
AT	21	Lengauer, C., et al., "Genetic instabilities in human cancers," <i>Nature</i> 396:643-649, Macmillan Journals Ltd. (1998)

EXAMINER	DATE CONSIDERED
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 0942.4980006/RWE/MTT		APPLICATION NO. 10/026, 152	
				APPLICANT Nazarenko et al.		OCT 15 2001	
				FILING DATE December 27, 2001		GROUP 1623	

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	22	Leone, G., et al., "Molecular beacon probes combined with amplification by NASBA enable homogeneous, real-time detection of RNA," <i>Nucl. Acids Res.</i> 26:2150-2155, Oxford University Press (1998)
	AS	22	Marras, S.A.E., et al., "Multiplex detection of single-nucleotide variations using molecular beacons," <i>Genetic Analysis: Biomolecular Engineering</i> 14:151-156, Elsevier Science B.V. (February 1999)
	AT	22	Monia, B.P., et al., "Selective Inhibition of Mutant Ha-ras mRNA Expression by Antisense Oligonucleotides," <i>J. Biol. Chem.</i> 267:19954-19962, American Society for Biochemistry and Molecular Biology, Inc. (1992)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	23	Moran, S., et al., "Non-hydrogen bonding 'terminator' nucleosides increase the 3'-end homogeneity of enzymatic RNA and DNA synthesis," <i>Nucl. Acids Res.</i> , 24:2044-2052, Oxford University Press (1996)
	AS	23	Newton, C.R., et al., "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)," <i>Nucl. Acids Res.</i> 17:2503-2516, IRL Press (1989)
	AT	23	Serra, M.J. and Turner, D.H., "Predicting Thermodynamic Properties of RNA," <i>Meth. Enzymol.</i> 259:242-261, Academic Press, Inc. (1995)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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OCT 15 2002

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	24	Tyagi, S., et al., "Extremely sensitive, background-free gene detection using binary probes and Q $\beta$ replicase," <i>Proc. Natl. Acad. Sci. USA</i> 93:5395-5400, National Academy of Sciences (1996)
	AS	24	Tyagi, S., et al., "Multicolor molecular beacons for allele discrimination," <i>Nat. Biotechnol.</i> 16:49-53, Nature Publishing Group (1998)
	AT	24	Vet, J.A.M., et al., "Multiplex detection of four pathogenic retroviruses using molecular beacons," <i>Proc. Natl. Acad. Sci. USA</i> 96:6394-6399, National Academy of Sciences (May 1999)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952
	APPLICANT Nazarenko et al.	
	FILING DATE December 27, 2001	GROUP 1623

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OCT 15 2002

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	25	Whitcombe, D., et al., "Detection of PCR products using self-probing amplicons and fluorescence," <i>Nat. Biotechnol.</i> 17:804-807, Nature Publishing Group (August 1999)
	AS	25	Wittwer, C.T., et al., "Continuous Fluorescence Monitoring of Rapid Cycle DNA Amplification," <i>Biotechniques</i> 22:130-131,134-138, Eaton Publishing Co. (1997)
	AT	25	Zubritsky, E., "Pinning Down PCR," <i>Analytical Chemistry News &amp; Features</i> 71:191A-195A, American Chemical Society (March 1999)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**RECEIVED**

In re application of:

Nazarenko *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the  
Detection and Discrimination of  
Nucleic Acids**

Confirmation No. 7365

OCT 15 2002

Art Unit: 1623

Examiner: *To be assigned*

TECH CENTER 1600/290

Atty. Docket: 0942.4980006/RWE/MTT

**Fifth Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fifth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fourth Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

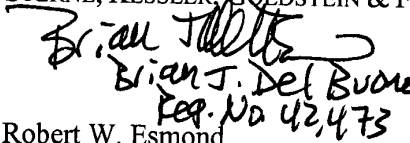
Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Fifth Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
for: Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893  
Fee No 42,473

Date: October 11, 2002

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FORM PTO-1449 FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4980006/RWE/MTT	APPLICATION NO. 10/026,952	<b>RECEIVED</b> OCT 15 2002 TECH CENTER 1600/2900
	APPLICANT Nazarenko et al.		
	FILING DATE December 27, 2001	GROSS 1623	

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	26	Hu, X., et al., "Fluorescence-Based Single-Tube Assays to Rapidly Detect Human Gene Mutations," <i>Strategies</i> 13:71-73, Stratagene (March 2000)
AS	26	Nazarenko, I., et al., "Multiplex quantitative PCR using self-quenched primers labeled with a single fluorophore," <i>Nucl. Acids Res.</i> 30:e37 (seven pages), Oxford University Press (April 2002)
AT	26	Nazarenko, I., et al., "Effect of primary and secondary structure of oligodeoxyribonucleotides on the fluorescent properties of conjugated dyes," <i>Nucl. Acids Res.</i> 30:2089-2095 (May 2002)

EXAMINER	DATE CONSIDERED
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	